

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

H. LUNDBECK A/S, TAKEDA)	
PHARMACEUTICAL COMPANY LTD.,)	
TAKEDA PHARMACEUTICALS U.S.A.,)	
INC., TAKEDA PHARMACEUTICALS)	
INTERNATIONAL AG, and TAKEDA)	
PHARMACEUTICALS AMERICA, INC.,)	
)	C.A. No. 18-88-LPS
Plaintiffs,)	CONSOLIDATED
)	
v.)	PUBLIC VERSION
)	
APOTEX INC., et al.,)	
)	
Defendants.)	

**LUPIN'S LETTER BRIEF IN SUPPORT OF EXPEDITED MOTION TO
ENFORCE PRIOR ORDER AND RENEWED MOTION TO STRIKE
PORTIONS OF PLAINTIFFS' EXPERT REPORTS**

Dated: August 13, 2020

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Limited and Lupin Pharmaceuticals,
Inc.*

Dear Chief Judge Stark:

Pursuant to Section 10 of the Court's July 9, 2018 Scheduling Order (D.I. 31), the Lupin Defendants respectfully submit this letter brief in support of their expedited motion requesting enforcement of relief this Court already granted: Plaintiffs cannot belatedly allege during expert discovery a 'new form' theory of infringement, i.e., the presence of the [REDACTED] of vortioxetine hydrobromide in Lupin's ANDA product. (D.I. 801, "Order".) In a brazen affront to that Order, Plaintiffs continue to allege the presence of the [REDACTED] against Lupin. And, this time, they apparently conducted new testing *after* the Order to support their claims. There is no justification for such conduct. For that reason, Lupin renews its previously granted motion to strike (D.I. 747, "Prior Motion") and moves for enforcement of this Court's previous Order and a ruling that any opinions and evidence related to or alleging the presence of the [REDACTED] in Lupin's ANDA product are, and remain, stricken. Because Lupin has been forced to approach the Court yet again on this issue, Lupin also respectfully requests that it be awarded its reasonable attorneys' fees in doing so. Lupin further requests expedited consideration of this relief as the deposition of one of the experts who authored one of the partial stricken reports in question, Dr. Allan S. Myerson, is scheduled for August 27, 2020.

I. Background – The facts concerning this dispute are detailed in the parties' prior motion and briefing thereon. (D.I. 747, 748, 756, 764.) A brief summary is as follows: Plaintiffs never once alleged the presence of the [REDACTED] in Lupin's ANDA product—not in contentions (initial or final) or otherwise. Rather, for the first time in opening expert reports, Plaintiffs alleged that Lupin's ANDA products contain the [REDACTED] in addition to the [REDACTED].

Lupin filed its Prior Motion, seeking to strike the [REDACTED] theory, on May 6, 2020 (D.I. 747, 748). The relief sought by Lupin's Prior Motion was clear: "Lupin therefore requests that any expert opinions relating to, or alleging the presence of, the [REDACTED] in Lupin's ANDA products be stricken." (D.I. 748 at 3.)

This Court granted Lupin's Prior Motion by Oral Order on June 25, 2020.¹ As this Court explained:

Plaintiffs' parroting of Markush group claim language did not, in the context of the entirety of Plaintiffs' disclosures throughout this case (including especially the final infringement contentions), give these Defendants fair and timely notice that they were accused of infringement due to the presence of potentially every component of that group, and Plaintiffs have no persuasive explanation for taking until a month after final contentions were due (and many months after sample products were provided to and then tested by Plaintiffs) before adding the challenged contention in an expert report; allowing this new contention now would unduly prejudice Lupin and Macleods (who could have approached their infringement and/or invalidity cases differently had Plaintiffs made the new form allegation during fact discovery); nor do the other Pennypack factors help Plaintiffs (who can still proceed on their other timely-asserted claims of infringement of the '630 patent, who appear

¹ The Court granted a similar motion involving the [REDACTED] filed by the Macleods Defendants.

to have acted in willful disregard of their final infringement contentions deadline, and who have prejudiced and surprised these Defendants in a way that cannot easily be cured without disrupting the trial schedule);

(D.I. 801.) The [REDACTED] was then out of the case. But, Plaintiffs chose to proceed anyway.

Over five weeks after the Order, on July 31, 2020, Plaintiffs served two expert reports from Drs. Myerson and Morin—the same experts that submitted the reports that were the subject of Lupin’s first motion. Drs. Myerson and Morin once again offered opinions regarding the alleged presence of the [REDACTED] in Lupin’s ANDA product. In fact, with this Court’s Order *already in hand*, Plaintiffs had Dr. Morin perform testing on a [REDACTED]² that was never tested prior to, or otherwise the subject of, his opening report.³ Dr. Myerson in turn relies on this testing to allege the presence of the [REDACTED] in Lupin’s ANDA product, again.

Lupin promptly sought an explanation for Plaintiffs’ actions clearly flouting this Court’s directive. In response, Plaintiffs contend they are permitted to maintain their [REDACTED] theory:

Judge Stark granted Lupin’s motion to strike the [REDACTED], but he was clear that Plaintiffs “can still proceed on their other timely-asserted claims of infringement of the ’630 patent.” D.I. 801. Claim 1 of the ’684 patent, claims 5 and 7 of the ’355 patent, and claim 1 of the ’630 patent have been asserted since 2018 and have been identified in each of Plaintiffs’ infringement contentions. Consistent with Judge Stark’s order, Plaintiffs will continue to assert and present evidence of Lupin’s infringement of the full scope of these claims.

(Ex. 1, Email from S. Raiola.)⁴ Following a meet and confer, Lupin brought the instant motion.

II. This Court’s Prior Order Should be Enforced and the [REDACTED] Opinions Should be Stricken, Again – Plaintiffs disregard the spirit of this Court’s prior Order striking the [REDACTED] opinions. Plaintiffs served not one, but two separate reply reports reiterating opinions regarding the presence of the [REDACTED] in Lupin’s ANDA products. In the course of doing so, Plaintiffs’ counsel clearly requested that Dr. Morin perform testing on [REDACTED] after this Court’s Order prohibiting them from proffering such opinions. When pressed for an explanation, they unequivocally stated that “Plaintiffs will continue to assert and present evidence of Lupin’s infringement of the full scope of these claims.” (Ex. 1.) This position is deeply troubling.

First, it is clear that Lupin’s Prior Motion sought relief in the form of striking any opinions or evidence related to the [REDACTED], and this Court granted that relief. Through Plaintiffs’

² This is a [REDACTED] and tested by Dr. Morin in order to facilitate [REDACTED].

³ Indeed, Dr. Morin did test [REDACTED] prior to issuing his opening report.

⁴ As recognized in the Court’s Order, Plaintiffs’ 2018 contentions only parroted claim language.

attempted side-step of this Court's Order, Lupin is left no option but to seek a second order from the Court. Although front and center in Lupin's Prior Motion, Plaintiffs appear to believe the [REDACTED] opinions in the opening reports are still in evidence and were not actually stricken by this Court. Does Lupin still have to defend against those opinions even though the Prior Motion was successful? Although obvious, Plaintiffs must again be told "no." Plaintiffs failed to disclose any theory related to the [REDACTED] in discovery, at any point—whether its presence directly establishes infringement or whether its presence somehow supports another, undisclosed theory of infringement. For the same reasons, their attempt to revive the argument should fail here.

Second, Lupin is now facing a new prejudice never before at issue—trying to determine what, if anything, Plaintiffs actually contend Lupin infringes in this case. Plaintiffs intend to "assert and present evidence of Lupin's infringement of the *full scope of these claims*." (Ex. 1.) Claim 1 of the '684 patent, for example, claims 17 different forms of vortioxetine. (Ex. 2, '684 patent.) And Plaintiffs believe this Court's Order permits them to assert "the full scope" of that claim. Are Plaintiffs asserting infringement of other forms they have never before disclosed? Do Plaintiffs now contend that the [REDACTED] is relevant for some other purpose? Must Lupin now defend against unarticulated theories regarding the presence of a number of different crystal forms in its product? Surely, this Court's prior Order was not an invitation to both reassert the [REDACTED] while threatening the assertion of the full scope of these very broad claims based on theories never before disclosed.

The third issue goes to Plaintiffs' apparent intention to proceed as they have. In their opening reports served April 16, 2020, Dr. Myerson and Morin (improperly) alleged the presence of the [REDACTED] in Lupin's ANDA products. While they did test [REDACTED] of vortioxetine hydrobromide, they did not analyze or test [REDACTED] in their opening reports. On June 25, 2020, this Court granted Lupin's motion to strike those [REDACTED] opinions. *The very next day*, [REDACTED], which arrived on June 29, 2020. Dr. Morin performed testing on the sample a week later on July 5, 2020.⁵ All of this occurred *after* this Court's Order striking the [REDACTED] opinions, yet Plaintiffs persisted. Putting aside the offense to this Court's prior Order, introducing this evidence for the first time in a reply report is highly improper. Plaintiffs should not be permitted to assert for the first time during expert discovery, a previously undisclosed infringement theory, lose a motion to strike on that theory, and then reassert that theory with newly created evidence in a reply report.

Plaintiffs must stop wasting Lupin's and this Court's time trying to remedy their own discovery failures (in this case, unilaterally, and in opposition to this Court's Order). But because they have been undeterred by this Court's prior Order, Lupin is now forced to approach the Court on this issue once more. Under these circumstances, Lupin respectfully makes the following requests: (1) that, consistent with its Prior Motion, any and all evidence asserting or otherwise alleging the presence of the [REDACTED] in Lupin's ANDA product be stricken; and (2) that Lupin be awarded its reasonable attorneys' fees in connection with the preparation and filing of this motion, including any reply.

⁵ See Morin Reply Report (Exhibit D to Cover Motion) at ¶¶ 11-14, 17.

Respectfully submitted,

/s/ James M. Lennon

cc:

Clerk of Court (via CM/ECF)

All Counsel of Record (via e-mail)